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10/647,071	08/22/2003	Philip A. Swain	11662-003-999	9609

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EXAMINER	
STEELE, AMBER D	
ART UNIT	PAPER NUMBER
1639	
MAIL DATE	DELIVERY MODE
10/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,071	SWAIN ET AL.	
	Examiner	Art Unit	
	AMBER D. STEELE	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *125,126,128,131-138 and 142-160* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *125,126,128,131-138 and 142-160* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-99, 105-108, and 110 were canceled, claims 101-103 and 109 were amended, and new claims 111-124 were added in the amendment to the claims received on June 1, 2006.

The amendment to the claims received on February 16, 2007 amended claims 100-101, 118; canceled claims 102, 114-116; and added new claims 125-140.

The amendment to the claims received on October 9, 2007 canceled claims 100-101, 103-104, 109, 111-113, 117-124, 127, and 130 and amended claims 125 and 129.

The amendment to the claims received on June 12, 2008 amended claim 125, canceled claims 129 and 139-140, and added new claims 141-142.

The amendment to the claims received on January 26, 2009 amended claims 125-126, 128, 131-138, and 142 and canceled claim 141.

The amendment to the claims received on June 11, 2009 amended claims 125 and 142.

The amendment received on August 26, 2009 amended claims 125 and 126 and canceled claims 143-160. Please note: claim 132 has an improper status identifier. See the claim objection below.

Claims 125-126, 128, 131-138, and 142-160 are currently pending and under consideration.

Election/Restrictions

2. Applicants elected, with traverse, Group I (previous claims 100-104) in the reply filed on June 1, 2006. The traversal was on the ground(s) that a serious burden to search Groups I and III did not exist. The traversal was found persuasive. Therefore, the restriction between Groups I

and III (i.e. previous claim 109) was withdrawn. However, applicants did not traverse the restriction between Group I and Groups II or IV. The restriction was made final in the Office action mailed on August 17, 2006.

Priority

3. The present application claims status as a CON of 10/115,580 filed April 1, 2002 which is a CON of 09/882,803 filed June 14, 2001 which is a CON of 09/257,821 filed February 25, 1999 which is a CON of 08/720,487 filed September 30, 1996 (now U.S. Patent 5,876,727) which is a CIP of 08/563,673 filed November 28, 1995 (now U.S. Patent 5,760,184) which is a CIP of 08/414,971 filed March 31, 1995.

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/414,971, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 08/414,971 does not disclose nicotine

or nicotine derivatives (i.e. nicotine metabolites of present Figure 19, nicotine-1'-N-oxide, trans-3'-hydroxycotinine, or nicotine glucuronide). In addition, application No. 08/414,971 does not disclose branch CJ 11.

The disclosure of the prior-filed application, Application No. 08/563,673, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 08/563,673 (U.S. Patent 5,760,184 does not disclose nicotine derivatives (i.e. nicotine metabolites of present Figure 19, nicotine-1'-N-oxide, trans-3'-hydroxycotinine, or nicotine glucuronide).

Therefore, the priority date for the present claim limitations of nicotine derivatives and CJ 11 is September 30, 1996 (i.e. filing date of U.S. application 08/720,487 which is now U.S. Patent 5,876,727). The priority date for the claim limitation of nicotine is November 28, 1995 (i.e. filing date of U.S. application 08/563,673 which is now U.S. Patent 5,760,184). Therefore, the priority for the presently claimed invention as a whole is September 30, 1996.

Arguments and Response

5. Applicants contend that U.S. Patent 5,760,184 teaches nicotine derivatives excluding cotinine and point to column 6, lines 58-62 and column 18, lines 51-54. Applicants also contend that U.S. Patent 5,760,184 teaches CJ 11 via the disclosure that Q can be "another branch" and n is an integer thus CJ 7 [$Y(CH_2)_nQ$] where n is 0 and Q is CJ3 [$CO(CH_2)_nCOQ$] (see column 14, lines 23-25 and 44-45).

The columns citations indicated by applicants refer to cocaine derivatives or drug derivatives (i.e. not nicotine derivatives excluding cotinine). In addition, applicants state that n is zero. However, column 14 states that n is preferably from about 3 to about 20 (i.e. not zero).

Furthermore, the various different combinations (e.g. if Q is any other branch, etc. then hundreds of potential molecules could be created) would not specifically lead one of skill in the art to at once envisage CJ 11. See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) which states a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on August 26, 2009 is being considered by the examiner.

Invention as Claimed

7. A pharmaceutical composition comprising a hapten-carrier conjugate said pharmaceutical composition comprising at least one hapten which is nicotine or a nicotine derivative excluding cotinine and at least one carrier which is a pseudomonas exotoxin and wherein the hapten and the carrier are linked by a branch selected from the group of chemical moieties CJ 0, 1, 1.1, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, 11, and 11.1 and variations thereof.

Maintained Objection

Claim Objections

8. Claim 132 is objected to because of the following informalities: the claim has a status identifier of "Presently Amended" while the status identifier should be "Previously Presented". Appropriate correction is required.

Withdrawn Rejections

9. The rejection of claims 125-126, 128, 131-138, and 142 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) for "which elicit nicotine specific antibodies in a human" is withdrawn in view of the claim amendments received on August 26, 2009.

10. The rejection of claims 125-126, 128, 131-138, and 142 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) for "Q" is withdrawn in view of the support provided by applicants in the originally filed disclosure.

11. The rejection of claims 125-126, 128, 131-138, and 142 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the claim amendments received on August 26, 2009.

12. The rejection of claims 125-126, 128, 131-138, and 142 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for "a pharmaceutical composition which elicits nicotine-specific antibodies in a human" is withdrawn in view of the claim amendments received on August 26, 2009.

13. The rejection of claims 125-126, 128, 131-138, and 142 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention (i.e. nicotine derivative) is withdrawn in view of the claim amendments received on August 26, 2009.

New Rejections Necessitated by Amendment

14. Claims 126, 148, 152, 156, and 160 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed inventions. For example, the claims read "n is an integer preferably selected from about 3 to about 20". However, it is not clear if this requires the integer to be about 3 to about 20 or not. "[N] is an integer from about 3 to about 20" is suggested.

15. Claims 145, 149, 153, and 157 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 145, 149, 153, and 157, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). See sections (viii) and (ix) of the claims.

Maintained Rejections

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 125-126, 128, 131-138, and 142-160 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,876,727 alone or in combination with Green et al. U.S. Patent 5,601,831. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions as claimed in U.S. Patent No. 5,876,727 claim nicotine or nicotine-derived haptens conjugated to a carrier and pharmaceutical compositions of the hapten-carrier.

For present claims 125 and 142-160, U.S. Patent No. 5,876,727 claims a nicotine hapten-carrier conjugate comprising the structure shown in Figures 17b and 18 (e.g. nicotine derivative hapten wherein chemical moieties may be at positions A-F and not simply utilized as a linker between the hapten and the carrier) and side chains (e.g. branch) of CJ 0, 1, 1.1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, 11, and 11.1 (where the CJ structures are claimed, n = an integer, and Q is a carrier) and a T-cell epitope carrier (please refer to claim 1). In addition, U.S. Patent 5,876,727 claims carriers including peptides, proteins, cholera toxin, diptheria toxin, tetanus toxoid, and pertussis toxin (i.e. bacterial toxins; please refer to claim 1). Column 13, lines 45-49 of U.S. Patent 5,876,727 further defines T-cell epitope carriers as

pseudomonas exotoxin carriers. Alternatively, Green et al. teaches that pseudomonas exotoxin can be utilized as a carrier for hapten vaccines (see the entire specification particularly the abstract; columns 2, 10-12; claim 9).

For present claim 126, U.S. Patent 5,876,727 claims n is from 3 to 20 (please refer to claim 1).

For present claim 128, U.S. Patent 5,876,727 claims at least two haptens coupled to the carrier (e.g. greater than one hapten; please refer to claim 2).

For present claims 131-132, U.S. Patent 5,876,727 claims a pharmaceutically acceptable carrier, an aqueous solution at a physiologically acceptable pH, and adjuvants (e.g. pharmaceutically acceptable excipient; please refer to claims 8-11).

For present claim 133-135, U.S. Patent 5,876,727 claims alum (i.e. aluminum hydroxide), MF59, or RIBI adjuvants (please refer to claims 9-10).

For present claims 136 and 139, U.S. Patent 5,876,727 claims pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. auxiliary agent or supplementary active compound; please refer to claims 8-11).

For present claim 137, U.S. Patent 5,876,727 claims parenternal administration to a mammal (e.g. human; please refer to claims 12 and 17).

For present claim 138, U.S. Patent 5,876,727 claims oral administration (please refer to claims 12 and 18).

Therefore, the claims of U.S. Patent 5,876,727 render the presently claimed invention *prima facie* obvious.

Arguments and Response

18. Applicants' arguments directed to the rejection on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 5,876,727 for claims 125-126, 128, 131-138, and 142-160 were considered but are not persuasive for the following reasons.

Applicants contend that the rejection is improper because the rejection relies on the specification of U.S. Patent 5,876,727 and alternatively the disclosure of Green et al. Applicants contend that an obviousness-type double patenting rejection must be based on a comparison of the claims (i.e. specification or another reference may not be utilized).

Applicants' arguments are not convincing since the claimed invention of 5,876,727 renders obvious the pharmaceutical composition of the instant claims.

The analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. See *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991) and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). A secondary reference can be utilized in an obviousness type double patenting rejection.

The specification can be used as a dictionary to learn the meaning of a term in the patent claim (i.e. T-cell epitope is defined in the specification of U.S. Patent 5,876,727 to include pseudomonas exotoxin). See *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. See *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970).

Furthermore, it is noted that applicants attempted to file a terminal disclaimer for U.S. Patent 5,876,727 on August 15, 2008. However, the TD was not approved. Applicants are respectfully directed to MPEP § 14.29 and § 14.29.02.

19. Claims 125-126, 128, 131-138, and 142-160 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 88, 90, 103, 106, 108-109, and 128-135 of copending Application No. 11/472,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions claimed in U.S. Patent application 11/472,215 claim nicotine hapten-carrier conjugates and pharmaceutical compositions.

For present claims 125, 128, 131, and 142-160, U.S. application 11/472,215 claim a nicotine hapten or nicotine derivative hapten-carrier conjugate comprising the structure shown in Fig. 17b (e.g. nicotine derivative hapten) and branches of CJ 0, 1, 1.1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, 11, and 11.1 wherein Y (e.g. for the CJ structures) is S, O, or NH (where the CJ structures are claimed, n = an integer, and Q is a carrier) and a T-cell epitope carrier (please refer to claims 88 and 91). In addition, U.S. application 11/472,215 defines bacterial toxin carriers as including pseudomonas exotoxin (see the specification).

For present claim 126, U.S. application 11/472,215 claim n is from 3 to 20 (please refer to claim 90).

For present claims 132, U.S. application 11/472,215 claim adjuvants (please refer to claim 103).

For present claim 133, U.S. application 11/472,215 claim alum, MF59, or RIBI adjuvants (please refer to claims 106 and 108).

For present claim 134-135, U.S. application 11/472,215 claim aluminum hydroxide or aluminum phosphate (please refer to claim 108).

For present claim 136, U.S. application 11/472,215 claim pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. auxiliary agent or supplementary active compound; please refer to claims 103, 106, and 108).

For present claim 137, U.S. application 11/472,215 claim parenteral administration to a mammal (e.g. human; please refer to claims 109 and 128-135).

For present claim 138, U.S. application 11/472,215 claim oral administration (please refer to claims 109 and 128-135).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Arguments and Response

20. Applicants' arguments directed to the rejection on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 11/472,215 for claims 125-126, 128, 131-138, and 142-160 were considered but are not persuasive for the following reasons.

Applicants contend that the rejections should be held in abeyance.

Applicants' arguments are not convincing since the claimed inventions of 11/472,215 renders obvious the pharmaceutical composition of the instant claims. In addition, while a request may be made that objections or requirements as to form not necessary to further

consideration of the claims be held in abeyance until allowable subject matter is indicated, the present is a rejection and will not be held in abeyance (see MPEP § 714.02).

21. Claims 125-126, 128, 131-138, and 142-160 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 119-135 of copending Application No. 11/472,220. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention is drawn to a pharmaceutical composition which implies a method of treating/method of eliciting an immune response as claimed in U.S. application 11/472,220.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Arguments and Response

22. Applicants' arguments directed to the rejection on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 11/472,220 for claims 125-126, 128, 131-138, and 142-160 were considered but are not persuasive for the following reasons.

Applicants contend that the rejections should be held in abeyance.

Applicants' arguments are not convincing since the claimed inventions of 11/472,220 render obvious the pharmaceutical composition of the instant claims. In addition, while a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated, the present is a rejection and will not be held in abeyance (see MPEP § 714.02).

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639